

For interview

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In re patent application of

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Group Art Unit: 1642

Serial No. 09/256,237

Examiner: M. Davis

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For: NUCLEIC ACID CONSTRUCT FOR EXPRESSING ACTIVE SUBSTANCES
WHICH CAN BE ACTIVATED BY PROTEASES AND PREPARATION AND USE

Pending Claims

21. A method for preparing a polypeptide said polypeptide of claim 25, comprising transducing a suitable cell with said construct, expressing said polypeptide in said cell, and isolating said expressed polypeptide.

23. The method of claim 21, wherein said cell is an endothelial cell, a lymphocyte, a macrophage, a glia cell, a fibroblast, a liver cell, a kidney cell, a muscle cell, a cell of the bone or cartilage tissue, a synovial cell, a peritoneal cell, a skin cell, an epithelial cell, a leukemia cell or a tumor cell.

25. (Thrice Amended) A polypeptide encoded by a nucleic acid construct comprising the following nucleic acid sequences in the following order:

- a) at least one promoter element operably linked to;
- b) at least one nucleic acid sequence which encodes an active compound, wherein said active compound is endogenous to mammals, operably linked to;
- c) at least one nucleic acid sequence which encodes an amino acid sequence cleavable specifically by a protease which is released at or from a mammalian target cell, operably linked to;
- d) at least one DNA sequence which encodes a polypeptide which is bound to said active compound by said cleavable amino acid sequence and inhibits the activity of said compound,

wherein said polypeptide comprises the active compound or compounds of b), the cleavable sequence or sequences of c), and the inhibitor or inhibitors of d), and wherein

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said nucleic acid component c) does not naturally occur as operably linking said nucleic acid sequence b) to said nucleic acid d).

26. The polypeptide of claim 25, wherein said active compound is human factor X (FX), in which amino acid 194 has been mutated from Arg to Tyr.
27. The polypeptide of claim 26, wherein said promoter element a) comprises the promoter sequence of the cdc25C gene, the sequence GCCACC, and the cDNA for an immunoglobulin signal peptide; and wherein component b)c)d) comprises the cDNA for human factor X (FX), in which amino acid 194 has been mutated from Arg to Tyr.